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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/484,786	06/07/1995	BERNARD F. MACH	MACH-2-CONT.	4894

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EXAMINER
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ART UNIT	PAPER NUMBER
1655	32

DATE MAILED: 11/16/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/484,786	Applicant(s) MACH ET AL.	
	Examiner Lisa B. Arthur	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *26 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *76-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *76-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. *06/518,393* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *29* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. This action is in response to the paper filed on January 26, 2001 . Claims 51-75 have been canceled and replaced with claims 76-102. All of the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance for the reasons which follow. Any rejections which have not been reiterated have been withdrawn from consideration. This action contains new grounds of rejection.

MAINTAINED REJECTIONS

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 76-102 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,503,976. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of patent 5,503,976 are drawn to a specific embodiment, i.e. methods and kits using specific 19-mer oligonucleotides, which are encompassed in the more broadly drawn claims of the instant application.

This rejection is maintained pending the filing of a terminal disclaimer.

NEW GROUNDS OF REJECTION

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 76-79, 82-102 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 76-77 are broadly drawn to an HLA-DR typing method by hybridizing a DNA sample with a sequence that can hybridize to a polymorphic region of an HLA-DR-beta chain locus wherein the sequence encodes amino acids 8-14,26-32 and 72-78. Claims 78-79 are broadly drawn to an HLA-DR typing method in which sample DNA is hybridized to a DNA sequence encoding "a majority" of the region defined by amino acids 8-14,26-32,39-45 or 72-78 of a polypeptide encoded by DR-beta-A, DR-beta-B or DR-beta-C or allelic variants. Claims 86,87-93 are dependent upon these claims. Claims 94-102 are drawn to kits containing a sequence that can hybridize to a polymorphic region of an HLA-DR-beta chain locus wherein the polymorphic region encodes amino acids 8-14,26-32 and 72-78 and allelic variants or a sequence which can hybridize to a conserved region of an HLA-DR-beta locus at amino acids 39-45.

The specification has described polynucleotides consisting of DR-beta-A, -B-and C and describe the regions within the polypeptide encoded by these polynucleotides, i.e. amino acids 8-14, 24-32 and 72-78 which are variable between -A, -B and -C and a region which is conserved between -A, -B and -C, i.e. amino acids 38-45 and describes methods of using these polynucleotides for HLA-DR typing. However, the claims, as written, encompass polynucleotides and methods of using polynucleotides that vary substantially in length and also in nucleotide composition. Since the specification has only described three specific DR-beta sequences and because the genus of sequences encompassed by the recitation in the claims is enormous with no common structural feature, the three species described in the specification are not representative of the genus. Furthermore, the prior art does not provide compensatory structural or correlative teachings to enable the skilled artisan to identify the DNA sequences encompassed for use in the method.

The claims encompass typing methods in which the DNA minimally encoding amino acids 8-14, 26-32 or 72-78 of any HLA-DR-beta chain is used to determine one or more HLA alleles. However, the specification has only described three specific DR-beta chain coding sequences. Because of the polymorphic nature of these genes, there may by many different DR-beta chain sequences of which three is not representative. Furthermore, the claims, as written encompass using genomic sequences as well as the cDNA sequences but the genomic DNA sequence has not been described in the specification to establish that applicant was in possession of genomic sequences at the time of filing. Additionally, the claims are drawn to method using DNA sequences which are capable of hybridizing to polymorphic sequences which makes the genus of

DNA sequences which can be used in the method even larger. Sequences identified by hybridization would not predictably have the same structural and functional characteristics as the disclosed species because there is no way to determine what variations would be tolerated without making the method inoperable as a typing method.

Claims 78-79 are not supported by the description in the specification because the claims encompass typing method using a DNA sequence which minimally, encodes "a majority" of a region of amino acids 8-14, 26-32, 39-45 or 72-78 of HLA-DR-beta -A, -B, -C or allelic variants. The DNA sequences used in the claim methods include a very large genus of sequences including genomic sequences, coding sequences for DR-beta chains different from those described in the sequence as well as sequences which do not encode DR-beta chains as a result of the vague language used in (a) of claim 57 and © of claim 58. The claims are not limited to the DNA sequences consisting of the specifically described regions of amino acids 8-14, 26-32, 39-45 and 72-78 of DR-beta, A, -B and -C of this application, but instead encompass large DNA sequences which only contain a few of the amino acids from these regions. The DNA sequence is not even limited to coding for the same amino acids as in the described regions because the claims recite that DNA encodes a majority of the region defined by amino acids. This statement is not the same as saying that the DNA encodes a majority of the amino acid sequence in the region of amino acids .... of nucleic acid X. Consequently, the claims are broadly drawn to a huge number of different typing methods using completely different probes when only three specific DR-beta chain sequences have been described. These three sequence do not constitute a representative number of species of the genus due the high degree of variability in the structures and functions of

the DNAs encompassed by the genus and the lack of a common structural feature of the elements of the genus.

Claims 94-98 are drawn to typing kits that contain the same genuses of DNA sequences as claimed in the typing methods discussed above and lack sufficient description for the same reasons as given above.

Thus, the written description of the instant specification only provides support for a typing method using the polynucleotides of DR-beta-A, B or -C or polynucleotides consisting of the specifically described polymorphic regions of DR-beta-A, B or -C and the specifically described conserved region, i.e. the method for which a patent was granted in patent 5,503,976. However, the full breadth of the claims to not meet the written description provision of 35 USC 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 1115) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Application under the 35 USC 112, first paragraph"written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday, December 21, 1999.

Response to Arguments

The response traverses the rejection on the following grounds. The response argues that the claims have been amended to clarify the scope of the invention. Specifically, the response point to the amendment of the claims to recite that the DNA sequences hybridize to specifically defined polymorphic region of an HLA-DR-beta chain locus. This amendment of the claims has

been thoroughly reviewed but does not limit the claims to the embodiments described in the specification because (1) any DNA molecule can hybridize to any other DNA molecule under low stringency hybridization conditions and (2) a DNA which can hybridize to a polymorphic region has no length limitation and as written encompasses the full length DR-A, DR-B and DR-C which would not be expected to be useful for typing.

6. No claims are allowable.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa Arthur whose telephone number is (703) 308-3988. The examiner can normally be reached on Monday-Wednesday from 7:00 am -2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

LISA B. ARTHUR
PRIMARY EXAMINER
GROUP 1800

November 14, 2001